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EXAMINER	
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1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,348	EGGERSDORFER ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3 - 6, 13 - 19, 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3 - 6, 13 - 19, 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed February 11, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 – 1st Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 2, 26 and 27 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Due to the amendments to the claims, this rejection is WITHDRAWN.

3. Claims 26 and 27 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of type 2 diabetes, does not reasonably provide enablement for the treatment of type 1 diabetes or the prevention of type 2 diabetes. The treatment of type 1 diabetes has been deleted from claim 26 and claim 27 has been cancelled.

Applicant traverses the scope of enablement rejection for the prevention of type 2 diabetes because the art acknowledges that conceptually, prevention is no different from treatment and that in the examples provided in the specification, lower blood glucose levels were observed in a diabetes mouse models. Applicant also states on p 11 of the remarks that “the specification provides example and evidence that the compositions recited in the claims prevent the appearance of type 2 diabetes in model systems.”

These arguments are deemed not be persuasive. The Examiner was unable to find any evidence in the specification that the compositions were administered to a model system and that none of the subjects ever developed diabetes. Example 12 uses a mouse model of late type 2 diabetes and therefore already have the disease. In that example, blood glucose levels were moderated and thus, a composition comprised of biotin and phytanic acid was shown to be useful in the treatment of type 2 diabetes. It is noted that this combination has been excluded from the claims. Example 13 relates to the level of gene expression in liver tissue culture cells and how the level of one gene associated with glucose homeostasis changes. It was not indicated if this system is a diabetic model system. If the Examiner is not interpreting the experiments presented in examples 12 and 13 appropriately, a detailed explanation of the examples and the data referred to on page 11 of the response would be greatly appreciated. Also, it is unclear that if “treating” and "preventing” are no different, as alleged, why both terms are recited in the claims.

As put forth in the office action, "prevent" is defined to mean that one will never develop a particular condition. As the full text of the reference that acknowledges that "treating" and "preventing" as conceptually equal was not submitted, the Examiner is unable to evaluate the full context of this statement. A conceptual equivalence is not sufficient. Even if data showing administration of the composition to a model system at risk for developing diabetes was prevented by the administration of biotin and a second ingredient, the data would be from a limited time frame. It would not demonstrate that none of the subjects not only did not develop diabetes during the course of the experiment but also that the subjects never developed diabetes. Also, diabetes prevention is not the relative state of the art, as such treatment is not usually given in the art until diabetes has been diagnosed. There are a myriad of risk factors and physiological conditions that are involved in the development of diabetes and due to this the state of the art of preventing diabetes is not established.

Since the term "treating" is inclusive of various administrative timing schemes and thus provides adequate coverage for all reasonably successful therapies (prophylactic or active), the examiner recommends deleting the term "preventing" and simply reciting "treatment" only instead.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, 5, 6, 20, 26 and 27 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Due to the amendments to the claims, this rejection is WITHDRAWN.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 13, 16 and 17 were rejected under 35 U.S.C. 102(b) as being anticipated by Reddi et al. (Life Sci 1998).

Applicant's arguments have been fully considered and are persuasive. The rejection of August 9, 2007 has been WITHDRAWN.

8. Claims 13 – 15 were rejected under 35 U.S.C. 102(b) as being anticipated by Coggeshalle (An NY Acad Sci, 1985).

Applicant's arguments have been fully considered and are persuasive. The rejection of August 9, 2007 has been WITHDRAWN.

9. Claims 9 and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Fine (US 6,203,819).

This rejection is MOOT in light of the cancellation of claims 9 and 10.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 3 and 4 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek (US 6,103,756).

Applicant's arguments have been fully considered and are persuasive. The rejection of August 9, 2007 has been WITHDRAWN.

12. Claims 1 – 4, 26 and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reddi et al. in view of Cincotta et al. (US 5,714,519). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 9, 2007 and those set forth below. Due to the amendments to the claims, this rejection is now applied to claims 1, 3, 4, 13, 16, 17 and 26.

Applicant traverses this rejection on the basis that Reddi teaches away in view of the disclosure on p 1329 in which high-dose biotin treatment (a dosage outside the

claims of the instant application) was ineffective in lowering blood glucose levels in genetically obese diabetic db/db mice. Additionally, Applicant asserts synergism for combinations of biotin with phytanic acid, cystemaine and EGCG that is not hinted at or suggested by either of the references.

These arguments are deemed not to be persuasive. The dosage range of panthethine in the claims of the instant application overlap with the range recited by Cincotta et al. (about 15 to about 500 mg/kg of body weight; col 5, ln 6 – 10). The quote cited by Applicant refers to unpublished results and only states results in one model of diabetes with one dose. The reference is silent as to the effect of low dose biotin, the dosage investigated that falls within the limitation of that claimed by Applicant. The studies for which results are presented in Reddi et al. demonstrate that in KK mice, a different mouse model of diabetes, a dose of biotin of 2 mg/kg was effective in the treatment of diabetes. The summary clearly states that diabetic KK mice administered either 2 mg biotin/kg or 4 mg biotin/kg exhibited lowered post-prandial glucose levels, improved tolerance to glucose and insulin resistance in comparison to controls (summary, p 1323). A statement of one dosage in unpublished results not being effective in a different diabetes mouse model does not obviate the teachings presented elsewhere in the paper with data showing treatment of diabetes with a biotin dosage in the range claimed by applicant in diabetic KK mice. Also, Reddi et al. teaches once daily administration of biotin at 2 mg.kg og body weigh in 0.1 mL of liquid solution via a gastric tube (p 1324, ln 1 – 3). This falls with the range recited in claim 1 and the range recited in claim 17.

The following is a quote from MPEP 716.02(a):

> Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (i.e., demonstrating "synergism"). Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). However, a greater than additive effect is not necessarily sufficient to overcome a prima facie case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. Ex parte The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991) (emphasis added).

As this rejection relates to the combination of biotin and either panthethine or cysteamine, the discussion is restricted to those combinations relevant for this particular rejection. No data is presented for the combination of biotin with panthethine. Example 13 present data regarding the relative expression of the gene for the catalytic subunit of glucose-6-phosphatase, an enzyme involved glucose homeostasis. While Applicants have shown that the level of expression of this gene is lower than the expression level when biotin or cysteamine are administered alone, the standard deviations associated with each of these numbers are relatively large. It has also not been demonstrated that the level of gene expression when administered a combination of active ingredients is lower that the strictly additive effects of the individuals components and further, that this lowered gene expression level results in a significant and practical advantage. So while the alteration in gene expression may or may not be statistically significant, diabetes is a complex disease with many factors that determine whether or not an individual will develop diabetes and the severity of the disease so a change in the expression level of

one gene in liver tissue culture cells does not indicate a significant and practical advantage.

13. Claims 1, 2, 7, 8, 26 and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reddi et al. in view of Fleuhmann et al. (EP 1177789). Due to the amendments to the claims, this rejection is WITHDRAWN.

14. Claims 1, 2, 9, 10, 26 and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reddi et al. in view of Wessel et al. (US 6,117,899). Due to the amendments to the claims, this rejection is WITHDRAWN.

15. Claims 1, 2, 5, 6, 26 and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reddi et al. in view of Van Leare et al. (PGPub 2003/0004215). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 9, 2007 and those set forth below. Due to the amendments to the claims, this rejection is being applied to claims 1, 5, 6, 13 – 17 and 26.

Applicant traverses this rejection based on the teaching way of Reddi et al. by the lack of results with high dose biotin (higher than the range of the instant claims) in db/db mice. Applicant also argues that Van Leare discloses combinations of 2-hydroxy carboxylic acids with carbohydrase inhibitors, and that Van Leare discloses an extremely large genus and subgenus of carbohydrase inhibitors and that the Examiner has not met the burden of why EGCG would be selected over all others. The reasoning

of *In re Kerkhoven* is not applicable because the carbohydrase inhibitors of Van Leare et al. inhibits intestinal absorption of carbohydrates whereas Reddi et al. is concerned with treating diabetes with biotin and therefore the purposes are not the same. Additionally, Applicant asserts a synergistic beneficial effect in example 13 for the combination of EGCG with biotin.

These arguments are not found persuasive. As discussed in greater detail above, Reddi et al. does teach the efficaciousness of biotin in the treatment of diabetic KK mice and therefore does not teach away from the use of biotin to treat diabetes.

The claims of the instant language use the open language of comprising so the alpha-hyrdoxy carboxylic acids taught by Van Leare et al. are not excluded from the composition of the claims of the instant application.

Van Leare et al. states that a reduction in carbohydrate absorption in the intestine can be advantageous for subjects suffering from diabetes (paragraph [0003]). One characteristic of diabetes is high blood sugar levels, and those levels can be lowered by decreasing the amount of sugar that enters the blood in the first place. Therefore, the reasoning of *In re Kerkhoven* does apply, even though the compounds may not act on the same aspects or symptoms of diabetes. The combination of active ingredients that exert their effect on different parts or aspects of a particular disease is a reason to combine those two active ingredients into one composition. Van Leare et al. also states that solid dosage forms such as tablets and equivalent solid or semi-solid dosage forms can be used to administer the active ingredients (paragraph [0056]).

While a several carbohydrase inhibitors are disclosed, EGCG and the amount of EGCG that need be present in green tea extract for it to possess sufficient carbohydrase inhibitory action is disclosed (paragraph [0067]). "Polyphenols" is presented in a list of 10 items and within polyphenols, EGCG is explicitly mentioned, along with a dosage required to provide sufficient carobhydrase inhibitory effect (paragraph [0067]). Given this explicit disclosure, it is not persuasive to argue the extreme breadth of the genus and subgenus. While "carbohydrase inhibitor" and "polyphenol" encompass compounds outside those explicitly disclosed, the disclosure of Van Leare et al. explicitly discloses a relatively small number of species and the compound of interest, EGCG, is very clearly exemplified as carbohydrase inhibitor.

As to the synergistic effects, this argument was discussed in greater detail above. It has not been demonstrated that the level of gene expression for the EGCG and biotin combination is lower that the strictly additive effect of the individuals components on gene expression and further, that this lowered gene expression level results in a significant and practical advantage. So while the alteration in gene expression may or may not be statistically significant, diabetes is a complex disease with many factors that determine whether or not an individual will develop diabetes and the severity of the disease so a change in the expression level of one gene may not indicate a significant and practical advantage.

16. Claims 1, 11, 12 and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reddi et al. in view of Crespo (Int J Clin Pharmacol Res 1999). Due to the amendments to the claims, this rejection is WITHDRAWN.

17. Claims 18 and 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reddi et al in view of Pearson et al. (US 6,261,589). To clarify the previous action, claims 1, 18 and 19 are rejected over Reddi et al. and Cincotta et al. or Reddi et al. and Van Leare et al. in further view of Pearson et al. This rejection is made for the reasons of record set forth in the Office Action mailed August 9, 2007 and those set forth below.

Reddi et al. and either Cincotta et al. or Van Leare et al. teach a combination of biotin with panthethine, cysteamine or EGCG that are useful in the treatment of diabetes.

None of these references teach a composition in which these ingredients are used in a food, beverage, food supplement or beverage supplement.

As noted in the Office Action mailed August 9, 2007, Pearson et al. discloses a beverage that delivers active ingredients to a subject, bringing about the production of stimulation of the release of neurotransmitters and neuromodulators in the brain.

Applicant traverses this rejection by stating that the beverage prepared by Pearson et al. is disclosed to support the production of and release of neurotransmitters and neuromodulators in the brain and the composition disclosed does not contain any of the ingredients of the composition and therefore there is no motivation to combine.

These arguments are deemed not to be persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the composition of Pearson et al. can contain green tea, which contains polyphenols. A polyphenol found in green tea is EGCG (Van Leare et al., paragraphs [0062] - [0067]). The beverage of Pearson et al. is a carrier for active ingredients in order to produce a physiological effect in the individual ingesting the beverage. The active ingredients in the composition of Pearson et al. are designed to produce a physiological effect in the brain. The ingredients taught by Reddi et al. and either Cincotta et al. or Van Leare et al. are intended to have a physiological effect on the whole body. As Pearson et al. teaches a beverage as a carrier for active ingredients, one of ordinary skill in the art would use that teaching to develop a beverage as a carrier system for the biotin and either, EGCG, cysteamine or panthethine combination taught by Reddi et al. and either Van Leare et al. (EGCG) or Cincotta et al. (cysteamine or panthethine) as Pearson et al. teaches that beverages can act as suitable carriers for substances which alter the physiology of the body ingesting the beverage.

18. Claims 18 and 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reddi et al. in view of Holbrook. Applicant's arguments have been fully considered and are persuasive and this rejection is WITHDRAWN.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1, 3 – 6, 13, 18, 19 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25 – 28, 30, 31, 34 – 38, 42 – 44, 46, 47, 49, 53 and 54 of copending Application No. 10/533,858 in view of Fleuhmann et al. (EP 1177789). The claims of the instant application recite a composition compromising biotin in a specific dosage range and at least one component selected from the group consisting of cysteamine, EGCG and panthethine. The composition can be used in a method of treating diabetes.

Claims 25 – 28, 30, 31, 34 – 38 and 42 – 44 of '858 recite a composition comprising EGCG, panthethine and phytanic acid with intended use language for using the composition to treat diabetes. Claims 46, 47, 49, 53 and 54 recite a method of treating diabetes with a composition comprising EGCG, panthethine and phytanic acid. The intended use recitation must impart a structural difference to the composition in order to patentably distinguishable.

While the claims of the instant application use open language and both EGCG and panthethine may be present in the composition, phytanic acid is not present.

Fleuhmann et al. teaches the use of phytanic acid or a phytanic acid derivative in the treatment of type 2 (non-insulin dependent) diabetes (see abstract and claim 2).

The composition of the claims of the instant application is claimed as useful in the treatment of type 2 diabetes and the composition of Fluehmann et al. comprising phytanic acid are both taught as useful for the same purposes, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine them (see *In re Kerkhoven)*. Such a composition, and a method of treating diabetes with a composition comprising the same ingredients is the claimed subject matter of Application 10/533,858.

This is a provisional obviousness-type double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW